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Jon W. Dudas

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

Docket Number:	9551-019-27 PROV

INVENTOR(s)/APPLICANT(s)

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TITLE OF THE INVENTION (280 CHARACTERS MAX)

PORTABLE HAND PUMP FOR EVACUATION OF BLOOD

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☐ Specification *Number of Pages:* 10

☐ Other (specify): White Advance Serial Number Card

☐ Drawing(s) *Number of Sheets:*

METHOD OF PAYMENT

☐ Applicant claims small entity status.

☐ A check or money order is enclosed to cover the Provisional Filing Fees

☐ The Commissioner is hereby authorized to charge filing fees and credit any overpayment to Deposit Account Number 50-1442

PROVISIONAL FILING FEE AMOUNT **$80.00**

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

November 20, 2007
DATE

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PROVISIONAL APPLICATION FILING ONLY

13281 U.S. PTO

FEE TRANSMITTAL

Docket No.	9551-019-27 PROV
Serial No.	NEW PROVISIONAL APPLICATION
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Inventor(s)	HASAN ALAM, ET AL.
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1. ☐ Applicant claims small entity status.

☐ Charge any **UNDERPAYMENT** or credit any **OVERPAYMENT** in the indicated fees to Deposit Account No. 50-1442.

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2. ☐ Check enclosed.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee ($)	Fee Code	Fee ($)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80.00
				SUBTOTAL (1)	$80.00

2. EXTRA CLAIM FEES

tot. claims		-	20*	=	0	x	$9	=	0
ind. claims		-	3*	=	0	x	$43	=	0
☐	Multiple Dependent Claims						$145	=	

Large Entity		Small Entity		Fee Description
Fee Code	Fee ($)	Fee Code	Fee ($)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	84	2204	43	*Reissue independent claims over original patent
1205	18	2205	9	*Reissue claims in excess of 20 and over original patent
				SUBTOTAL (2) $0.00

* or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee ($)	Fee Code	Fee ($)		
1051	130	2051	65	Surcharge-late filing fee or oath	
1052	50	2052	25	Surcharge-late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English Specification	
1251	110	2251	55	1-mo. ext. of time	
1252	420	2252	210	2-mo. ext. of time	
1253	950	2253	475	3-mo. ext. of time	
1254	1480	2254	740	4-mo. ext. of time	
1255	2010	2255	1005	5-mo. ext. of time	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Appeal Brief	
1403	290	2403	145	Request for Oral Hearing	
1501	1330	2501	665	Utility/Reissue Issue Fee	
1502	480	2502	240	Design Issue Fee	
1504	300	1504	300	Publication Fee	
8001	3	8001	3	Advance Copy of Patent	
1460	130	1460	130	Petitions to the Commissioner	
1806	180	1806	180	IDS Submission	
8021	40	8021	40	Assignment recordation	
1801	770	2801	385	For Filing RCE	
1814	110	2814	55	Terminal Disclaimer	
OTHER (Indicate below):					
				SUBTOTAL (3)	$0.00

Name	Steven B. Kelber	Registration No.	30,073		
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Rev. 10/03

DOCKET NO: 9551-019-27 PROV

TITLE OF THE INVENTION

PORTABLE HAND PUMP FOR EVACUATION OF BLOOD

I. Brief Summary of the Technology Including Purpose and Use of the Invention

Manual suction devices are not available for use during the care of combat casualties. A hand held pump that can evacuate blood or air from the chest would be of benefit for casualties who have suffered injuries to the chest. This device could also be adapted for other uses such as: 1) checking correct placement of an endotracheal tube (tube placed in the wind pipe), 2) to suck out secretions from the mouth and to suck fluids out of drains that have been placed into various body cavities during surgery.

Currently, electrical or battery operated suction devices are available but due to the austere environment often faced by the military, having a suction device that does not have to rely on electricity or batteries would be of benefit, especially when transporting the patient. The evacuation and collection systems that are currently in use (such as Pleur-Evac device) are connected to tubes placed in the chest which drains blood and air. These collection systems use water seal as a one way valve and drainage is passive unless the system is connected to a suction source. The electrical suction devices available in the market are cumbersome and not suitable for use in the military environment and during transportation. Other one way valves are in existence but again they rely on gravity or increased pressure

in the chest to help push out undesired air or fluids. This newly developed manual suction device can pump large volumes of air, or fluid and can be useful while treating chest injuries as well as in other scenarios where a hand held suction device would be have benefit.

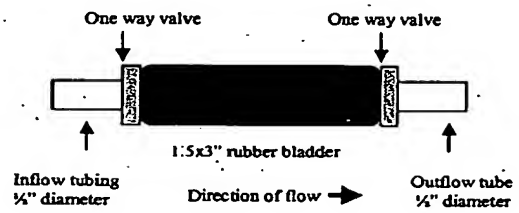
A swine model of penetrating chest injury was designed to test this concept. Our hypothesis was that a HP would be as effective as the standard of care for the evacuation of a large hemo-pneumothorax. We designed and tested this pump in a swine model of penetrating chest injury and bleeding in the pleural space. The prototype pump performed better than the standard of care.

II. Particular Features of the Invention That Are Novel Over Other Work

No similar device is commercially available to the best of our knowledge. The standard equipment used for the evacuation of blood and air from the pleural space is a large bore thoracostomy tube connected to negative pressure water seal devices (e.g. Pleur-Evacä device). The currently available drainage systems are cumbersome, bulky, and difficult to manage during transport. Furthermore, continuous suction source for the drainage system is often not available. While one way valves such as the Heimlich valves can be used, one distinct disadvantage is that by design they rely on gravity or increased intra-thoracic pressure for drainage, and do not provide suction to facilitate evacuation of blood/clots and re-expansion of the injured lung. A small, portable, easy to use hand pump (HP) that can be attached to a thoracostomy tube offers a major logistical advantage in austere environments. This hand pump does not require any wall suction, provides high

flow rates and effectively evacuates blood and clots from the pleural space. Attractive features for the military are the logistical advantages because the device is small, portable, lightweight, requires no wall suction, rigid containers, water or electricity and is adaptable (e.g. the out flow tube can be connected to an auto-transfusion unit). Again, there can be multiple uses for this device. Any circumstance where a manual hand pump is needed could be applicable. These instances includes attaching suction handles to suck out secretions out of the mouth, checking for correct tube placement when a tube has to be place in the windpipe, and to suck fluids out of drains which have been placed surgically. This device could also be used during surgery.

III. Detailed description of invention



A drawing of the pump is shown. Briefly, two pieces of clear vinyl tubing (4 inches in length and ½ inch inside diameter) were connected to a cylindrical rubber bladder (1.5x3 inch) using adaptors and two one-way valves. The position of the one-way valves on both ends of the rubber bladder ensured that fluid could

only move in one direction on squeezing the bladder (Figure). The inflow vinyl tubing was attached to the pleural evacuation tube whereas the outflow tubing was attached to a collection bag for the measurement of evacuated blood. In pilot trials this device was able to pump water at a maximum rate of 1L/minute. The negative pressure generated in the pleural tube (in vivo) was affected by the rate of pumping. A single pump generated negative pressure of 12mmHg and multiple successive pumps could generate a maximum pressure of -80-90 mmHg.

COMMERCIALIZATION

This device is very suitable for combat situations, during transport of injured soldiers, and for use in different echelons of military care. It would also be suitable for use by Emergency Medical Services during long transfers to the hospital or during inter-hospital transfer of patients with bleeding in the chest cavity. Any circumstance where a manual hand pump is needed could be applicable. These instances includes attaching suction handles to suck out secretions out of the mouth, checking for correct tube placement when a tube has to be place in the windpipe, and to suck fluids out of drains which have been placed surgically. This device could also be used during surgery for evacuating blood from the surgical field.

A Portable Handpump Is Effective in the Evacuation of Hemothorax in a Swine Model of Penetrating Chest Injury

Background: Standard pleural evacuation devices are not practical for use on the battlefield. A small, portable, easy-to-use handpump (HP) that does not require continuous suction for treating hemopneumothorax would offer a major logistical advantage. In addition, using endotracheal tubes instead of regular pleural tubes would help minimize supplies carried on the battlefield. A swine model of penetrating chest injury was designed to test this concept. Our hypothesis was that an HP would be as effective as the standard of care for the evacuation of a large hemopneumothorax.

Methods: A 2-cm lung laceration was created in 18 Yorkshire swine (35–51 kg) under inhaled anesthesia and 1.4 L of blood was infused into the pleural space (200 mL every 15 minutes). Fluid resuscitation (2,000 mL of 0.9% saline) was started 15 minutes after injury, and animals were randomized into one of three groups: group 1, 36-Fr Argyle pleural tube and Pleur-Evac chest drainage unit with 20-cm H_2O suction (control); group 2, 36-Fr pleural tube attached to the HP; and group 3, a No. 8 endotracheal tube in the pleural space attached to the HP. After 120 minutes, a thoracotomy was performed to determine the amount of residual blood in the pleural space.

Results: Effectiveness of the three methods as a percentage of total blood (evacuated and retained) removed was measured over 2 hours. The handpump (group 2) performed better than the standard of care (group 1) at numerous time points and evacuated significantly ($p < 0.05$) more blood at the end of the experiment.

Conclusion: Using the handpump with a pleural tube was more effective than the standard of care in treating traumatic hemothorax. The use of an endotracheal instead of a conventional pleural tube had no adverse impact on efficacy of the pump in evacuating blood from the chest cavity.

Key Words: Hemothorax, Pneumothorax, Lung injury, Handpump, Penetrating chest injury, Combat casualty, Battlefield.

Penetrating chest injuries have been a major cause of death on the battlefield.[1] Injured soldiers with hemopneumothorax need treatment as soon as possible. Whereas during the Vietnam War transport to a medical facility was rapid, it is predicted that evacuation may not be feasible for many hours during future conflicts. These military encounters are likely to have rapidly moving front lines and be in urban areas or on hostile, remote terrain.[2,3] All these conditions preclude rapid transportation to higher echelons of medical care. As seen in recent conflicts, logistical support has been limited near the front lines, and very long delays were encountered before the injured could be evacuated to a well-equipped facility.[4] Thus, the traumatic hemopneumothorax may have to be treated on the battlefield or in small mobile medical units. In addition to obvious problems associated with delays in transport, the injured may have to be transported multiple times (over long distances) before reaching the final treatment facility.

The standard equipment used for the evacuation of blood and air from the pleural space is a large-bore thoracostomy tube connected to negative-pressure water seal devices (e.g., Pleur-Evac device). The currently available drainage systems are cumbersome, bulky, and difficult to manage during transport. Furthermore, continuous suction for the drainage system is often not available. Although one-way valves such as the Heimlich valves can be used, one distinct disadvantage is that by design they rely on gravity or increased intrathoracic pressure for drainage and do not provide suction to facilitate evacuation of blood/clots and reexpansion of the injured lung.

A small, portable, easy-to-use handpump (HP) that can be attached to a thoracostomy tube would offer a major logistical advantage in austere environments. Our goal was to design such a device and test it against the standard thoracostomy drainage system in a swine model of penetrating lung injury that produced a hemopneumothorax. We hypoth-

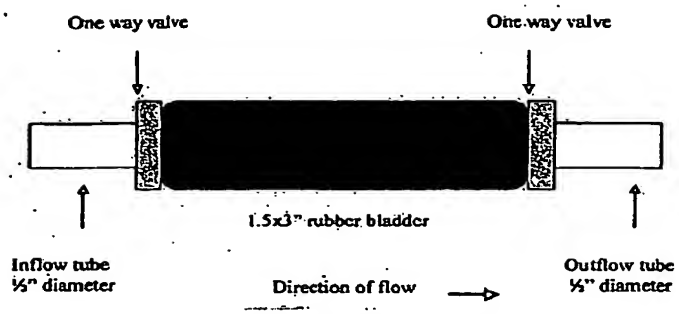


Fig. 1. *An illustration of the handpump device.*

esized that a simple HP would be as effective as the standard of care for the evacuation of large hemopneumothorax. To further limit the supplies that have to be carried by the first responder, we also decided to test the effectiveness of an endotracheal tube to drain the pleural cavity instead of a standard thoracostomy tube.

MATERIALS AND METHODS

The institutional animal care and use committee approved this study. All research was conducted in compliance with the Animal Welfare Act and other federal statutes and regulations relating to animals and experiments involving animals. The study adhered to the principles stated in the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 1996 edition). Strict aseptic technique was used for all surgical procedures. The experiment described in this article was performed in adherence to the guidelines of the institutional laboratory animal review board.

Description of the Handpump

This pump was assembled from commonly available hardware supplies. Briefly, two pieces of clear vinyl tubing (4 inches in length, with a ½-inch inside diameter) were connected to a cylindrical rubber bladder (1.5 × 3 inch) using adaptors and two one-way valves. The position of the one-way valves on both ends of the rubber bladder ensured that fluid could only move in one direction on squeezing the bladder (Fig. 1). The inflow vinyl tubing was attached to the pleural evacuation tube, whereas the outflow tubing was attached to a collection bag for the measurement of evacuated blood. In pilot trials, this device was able to pump water at a maximum rate of 1 L/min. The negative pressure generated in the pleural tube (in vivo) was affected by the rate of pumping. A single pump generated negative pressure of 12 mm Hg, and multiple successive pumps could generate a maximum pressure of −80 to −90 mm Hg.

Animal Preparation

Eighteen Yorkshire pigs (Tom Morris Farms, Reisertown, MD) weighing 35 to 51 kg were acclimated for 1 week before use and were fed a standard diet and had access to water ad libitum. The animals were deprived of food overnight before the experiment but allowed free access to water. Anesthesia was induced with an intramuscular injection of ketamine (10 mg/kg) and inhaled 5% isoflurane. The animals were placed supine on the operating table and, after placement of an endotracheal tube (7.5-mm; Baxter Healthcare Corp., Irvine, CA), the isoflurane concentration was reduced to 0.5% to 1% for the duration of the experiment. The animals were allowed to breathe room air spontaneously through a Narkomed M ventilator (North American Drager, Telfod, PA). The external jugular vein was cannulated with a 9-Fr introducer sheath using a cutdown technique. A 7.5-Fr oximetric thermodilution pulmonary artery catheter (Baxter Healthcare) was positioned through the introducer sheath. This line was used for hemodynamic monitoring and for administration of resuscitation fluids. The right carotid artery was cannulated with an 18-gauge over-the-needle catheter. Both catheters were connected to a hemodynamic monitoring system (Hewlett Packard, Palo Alto, CA) for continuous monitoring of the systemic and pulmonary artery pressures. A Baxter Explorer system (Baxter Edwards Critical Care, Irvine, CA) was used for continuous monitoring of mixed venous oxygen saturation, central venous pressure, pulmonary artery pressure, cardiac output, and calculated hemodynamic parameters. The catheters were flushed with 0.9% saline solution (10 mL/h) to maintain patency. Arterial and venous blood samples were analyzed on Nova Stat Profile Ultra (Nova Biomedical, Waltham, MA).

Creation of Lung Injury and Hemopneumothorax

To simulate penetrating chest injury, a 2-inch-long incision was made in the left seventh intercostal space over the lateral aspect of the chest wall and carried down sharply to the pleura. The thoracic cavity of the swine is shaped somewhat differently than that of humans and measures more in the anteroposterior dimension than lateral. A rib cutter was used to cut the rib at the dorsal aspect of the incision and the pleura was incised to expose the lung. At this point, the spontaneously breathing animal was switched to mechanical ventilation to match the baseline respiratory rate and tidal volume (no positive end-expiratory pressure). A 9-Fr introducer sheath was placed percutaneously in the anterior aspect of the fifth intercostal space and its position in the thoracic cavity was confirmed by palpation. This sheath was later used for introduction of blood into the pleural space. The inferior edge of the left lower lobe of the lung was grasped and a 1-0 silk stitch was passed 2 cm from the edge. The ends of the silk suture were brought out through the chest wall opening. At this stage, the animals were randomized into one of three groups, and the pleural evacuation tubes were placed through the chest wall opening and secured in place. The groups were as follows (n = 6 per group): group 1, Argyle straight thoracic catheter (36-Fr, Sherwood Medical, St. Louis, MO) connected to a Pleur-Evac adult chest drainage unit at −20 cm H_2O suction (Genzyme Biosurgery, Fall River, MA);

Table 1 Selected Hemodynamic and Physiologic Variables[a]

Variable	Groups	Time				
		Baseline	30 Min	60 Min	90 Min	120 Min
MAP (mm Hg)	1	77.33 ± 7.02	76.67 ± 6.96	54.67 ± 6.10	50.83 ± 3.96	51.00 ± 2.49
	2	79.67 ± 4.79	72.00 ± 4.91	63.00 ± 5.07	56.83 ± 6.26	50.67 ± 5.02
	3	80.33 ± 4.25	72.17 ± 6.38	64.83 ± 6.21	53.00 ± 7.27	51.50 ± 4.77
Ph	1	7.48 ± 0.02	7.44 ± 0.01	7.42 ± 0.01	7.41 ± 0.02	7.42 ± 0.02
	2	7.44 ± 0.01	7.41 ± 0.02	7.36 ± 0.02	7.37 ± 0.02	7.41 ± 0.02
	3	7.43 ± 0.01	7.40 ± 0.01	7.39 ± 0.01	7.39 ± 0.02	7.38 ± 0.02
BE (mmol/L)	1	6.63 ± 1.53	4.98 ± 2.39	5.7 ± 1.09	6.45 ± 1.94	7.85 ± 1.08
	2	6.68 ± 2.87	8.38 ± 1.55	6.7 ± 1.14	9.64 ± 1.25	7.78 ± 1.71
	3	5.91 ± 1.52	8.38 ± 1.24	6.92 ± 1.14	6.78 ± 0.87	5.62 ± 1.92
CO (L/min)	1	4.09 ± 0.35	4.78 ± 0.60	4.72 ± 0.46	3.91 ± 0.37	3.12 ± 0.17
	2	4.09 ± 0.38	4.26 ± 1.31	5.26 ± 0.61	4.37 ± 0.94	3.51 ± 0.31
	3	4.27 ± 0.42	5.62 ± 1.31	5.77 ± 1.18	4.42 ± 0.99	4.41 ± 1.26
Hg (g/dL)	1	9.03 ± 0.054	8.88 ± 0.74	7.18 ± 0.36	7.80 ± 0.43	8.75 ± 0.35
	2	8.37 ± 0.050	7.68 ± 0.34	6.36 ± 0.60	7.83 ± 0.71	7.52 ± 0.48
	3	8.93 ± 0.60	8.13 ± 0.59	6.74 ± 0.46	7.62 ± 0.70	7.98 ± 0.41
Lactate (mmol/L)	1	0.65 ± 0.13	0.72 ± 0.10	0.75 ± 0.13	0.60 ± 0.10	0.77 ± 0.09
	2	0.97 ± 0.31	0.70 ± 0.11	0.52 ± 0.08	0.67 ± 0.20	1.02 ± 0.20
	3	0.78 ± 0.07	1.32 ± 0.20	0.92 ± 0.16	1.05 ± 0.26	1.23 ± 0.30

MAP, mean arterial pressure; BE, base excess; Hg, hemoglobin B.

[a] Data are presented as group means ± SEM. Group 1, 36-F Argyle chest tube connected to Pleu-Evac chest drainage unit; group 2, 36-F Argyle chest tube connected to the prototype handpump; group 3, 8.0-mm endotracheal tube connected to the prototype handpump. Baseline = before hemorrhage and placement of pleural evacuation device; time = minutes from initiation of hemorrhage.

group 2, Argyle straight thoracic catheter (36-Fr) connected to the prototype hand pump; and group 3, an 8-mm endotracheal tube (Baxter Healthcare) connected to the HP.

After placement of all the lines and tubes, 100 mL of heparinized saline was flushed through the pleural evacuation system to confirm patency, after which all the pleural tubes were clamped. The balloon of the endotracheal tube was not inflated. At time zero, the silk stitch was pulled out to create a standardized lung injury and 200 mL of fresh blood (drawn through the arterial line) was infused into the pleural space through the previously placed 9-Fr sheath. Fifteen minutes later (mimicking time taken to obtain intravenous access and place pleural tubes), the clamps were removed from the pleural tubes and evacuation of hemothorax was started. In group 1, the pleural tube was subjected to a continuous negative pressure of 20 cm H_2O, whereas in groups 2 and 3 hand pumping was used as needed. At the 15-minute mark, intravenous fluid resuscitation was also started (2,000 mL of 0.9% saline over 1 hour). Every 15 minutes, another 200 mL of blood was withdrawn from the arterial line and infused into the pleural cavity until a total of 1.4 L of blood had been introduced. The blood evacuated from the thoracic cavity was recorded every 15 minutes for 2 hours. At the end of 2 hours, a standard anterolateral thoracotomy was performed through the fifth intercostal space. All the residual blood (and clots) in the left pleural space were evacuated and carefully weighed to record the unevacuated blood. The experiment was terminated at this point and animals were killed.

Statistical Analysis

All data are presented as group means ± SEM. The SPSS statistical software program (SPSS for Windows, SPSS Inc., Chicago, IL) was used to analyze data. Efficacy of the method was defined as the percentage of total blood evacuated after 120 minutes (total blood being defined as the evacuated plus the residual blood in the pleural cavity). One-way analysis of variance with Dunnett's test for multiple comparisons was performed (using group 1 as control). Significance was defined as $p < 0.05$.

RESULTS

All the animals survived the hemorrhage and the infusion of blood into the pleural space until the end of the experiment. There were no statistically significant differences in the measured hemodynamic and physiologic parameters between the groups (Table 1). The animals in all three groups were adequately resuscitated during blood withdrawal, and this is reflected by the absence of lactic acidosis or base deficit. These animals lost approximately 50% of total blood volume into the pleural cavity. The total amount of hemothorax (evacuated plus retained) was 1,436.5 ± 47.8 mL, 1,318.83 ± 101 mL, and 1,464.0 ± 21.85 mL in groups 1, 2, and 3, respectively. As the volume of blood introduced into the pleural space was identical for all groups, the differences reflect the variable amount of bleeding from the lung injury. However, these differences were statistically insignificant. The comparable hemoglobin levels at the end of experiment also attest to the fact that all the groups had lost a similar amount of blood.

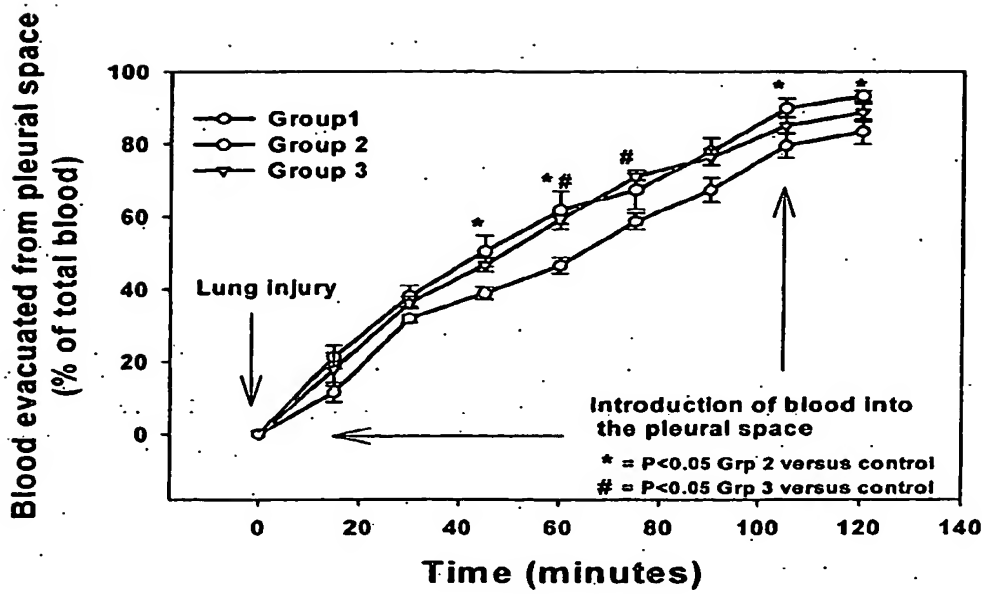


Fig. 2. *Blood evacuated from the pleural space over time (percentage of total blood). Data are presented as group means ± SEM. Group 1, 36-Fr Argyle chest tube connected to Pleur-Evac chest drainage unit; group 2, 36-Fr Argyle chest tube connected to the prototype handpump; and group 3, 8.0-mm endotracheal tube connected to the prototype hand pump.*

The HP used in conjunction with a chest tube (group 2) evacuated significantly more blood than the control group (Fig. 2). This difference became significant ($p < 0.05$) after 60 minutes and persisted until the end of the experiment. The animals in group 3 (endotracheal tube plus HP) also performed significantly better at the 60- and 75-minute marks; however, this difference disappeared by the end of the experiment. Interestingly, most of the animals (83.3%) in group 3 developed blood clots in the evacuation system (endotracheal tube and HP) at the 1-hour mark, which reduced flow and required mechanical removal of the blood clot. None of the animals in the other two groups formed clots large enough to affect blood flow through the system. The residual blood in the pleural space at the end of the experiment was 224.8 ± 36.50 mL, 87.16 ± 17.94 mL, and 159.05 ± 21.83 mL for groups 1, 2, and 3, respectively ($p = 0.014$, group 1 vs. group 2).

DISCUSSION

Our study has demonstrated that a simple handpump used with a standard pleural tube (or with an endotracheal tube in the pleural space) offers a viable alternative to the standard therapy. In contrast to the Pleur-Evac device, the HP did not require any wall suction, provided high flow rates, and effectively evacuated blood and clots from the pleural space. Although the handpump proved to be statistically more efficient than standard therapy, the goal of this study was not to prove the superiority of this pump but to explore logistically superior alternatives to the established therapy. Whether evacuating an extra 100 to 150 mL of blood alters the clinical outcome is debatable. However, the fact that this device is small, portable, and lightweight; requires no wall suction, rigid containers, water, or electricity; and is adaptable (e.g., the outflow tube can be connected to an autotransfusion unit) offers logistical advantages. Furthermore, the aim was to test the concept of a portable device for evacuation of traumatic hemothorax rather than a specific pump. We felt that if this rather crude device worked well, the next generation of devices can be designed to achieve even better performance while decreasing the size and weight. One limitation of this approach in the clinical setting would be the requirement for a dedicated person to manually use the pump. However, the device is easy to use and the pumping can be performed by a layperson (or even by the injured soldier him- or herself if stable). An additional point is that the device does not have to be pumped continuously. With the use of low-resistance valves, the device could act as a conduit for passive gravity drainage when not being pumped. Alternatively, it can be connected to a suction source when and if available. Furthermore, this study has shown that the use of an endotracheal tube instead of a standard chest tube can provide similar efficacy as the standard of care and is thus an acceptable temporizing measure.

Penetrating chest injuries resulting in hemopneumothorax have been very common during previous military conflicts.[5] The incidence of chest injuries may decrease in the future (as seen in Afghanistan) because of the common use of body armor by the soldiers,[6] but penetrating chest injuries

will still require some form of pleural drainage. The Heimlich valve offers a reasonable option for a simple pneumothorax[7,8] and pleural effusion;[9] however, these valves are of small caliber and thus not suitable for removal of blood clots. The feasibility of evacuating (and autotransfusing) fresh unclotted blood from the pleural space in dogs using a Heimlich valve-containing drainage system has already been demonstrated.[10] This animal model included simple hemothorax without any associated lung injury. By contrast, the animal model for the current study was designed to have chest wall trauma and lung laceration with an associated hemopneumothorax. The injuries included a 2-inch full-thickness chest wall defect, rib transection, 2-cm lung laceration, pneumothorax, and a very large hemothorax. The blood in the pleural space was introduced in a continuous fashion rather than as a single bolus, which is more representative of clinical bleeding. This model had some obvious limitations. There was no blast injury, the blood in the pleural space not only originated from the lung injury but was also introduced artificially, and the degree of pneumothorax was not standardized. In addition, the animals were sedated and mechanically ventilated during the experiment.

The higher efficacy of the handpump in evacuating a hemothorax may be attributable to the higher negative pressure generated. This negative pressure, however, does not seem to increase the bleeding and the degree of lung injury, at least on gross examination. Their may be several reasons for the high incidence of clot formation in group 3. First, a 36-Fr pleural tube has an internal diameter of 11.46 mm, 3.46 mm more than an 8.0-mm endotracheal tube (an 8-mm tube was chosen for its common availability). Because resistance is inversely proportional to the fourth power of the radius, the 8-mm endotracheal tube provided approximately nine times more resistance to flow than the chest tube. Second, a pleural tube has six openings for blood to go through, whereas the endotracheal tube has only two holes. These factors combined to increase stasis and thus clot formation, which became evident after 60 to 90 minutes. However, even with these disadvantages, the endotracheal tube performed reasonably well and may offer an alternative to traditional pleural tubes in an austere environment. The balloon on the endotracheal tubes was not inflated in this experiment to minimize the variables. It is possible that inflation of the balloon may improve the drainage by keeping the lung away from the drainage holes. With the encouraging results from this study, we are currently designing a new device, which would be smaller, lighter, and equipped with extremely-low-resistance valves. This should enhance the flow characteristics and further improve the logistical advantages.

In summary, in a swine model of penetrating chest injury, a prototype handpump was more effective than the standard of care in evacuating hemothorax. The use of an endotracheal tube instead of a conventional pleural tube had no major impact on efficacy. This approach could offer a portable and logistically superior alternative to the standard approach in austere battlefield environments.

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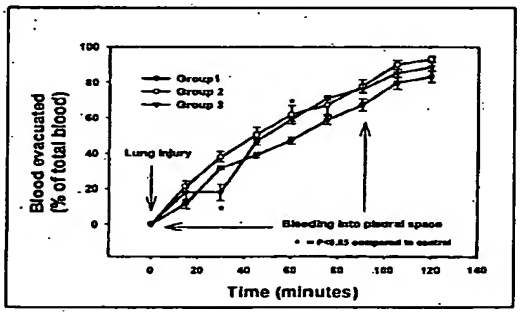
ABSTRACT

The use of standard pleural evacuation devices is not practical for battlefield use. A small, portable, easy to use hand pump (HP)that does not require continuous suction for treating hemo-pneumothorax would offer a major logistical advantage. Also using endotracheal tubes instead of chest tubes would help minimize supplies carried in the battlefield.

Methods: A 2 cm lung laceration was created in 18 Yorkshire swine (35-51 kg) under inhaled anesthesia and 1.4 liter of blood was infused into the pleural space (200 cc every 15 min). Fluid resuscitation (2000 cc of LR) was started 15 min following injury, and animals were randomized into one of three groups: 1) 36 F Argyle pleural tube and Pleur-Evac chest drainage unit with 20 cm water suction (control), 2) 36F pleural tube attached to the HP, 3) No 8 endotracheal tube in pleural space attached to the HP. After 120 minutes, a thoracotomy was performed to determine amount of residual blood in the pleural space.

Results: Effectiveness of the three methods as percent of total blood (evacuated and retained) removed is shown in the figure. There was no significant difference in the amount of blood evacuated at the end of the experiment between the groups.



Conclusion: Using the hand pump with a chest tube or an endotracheal tube was as effective as the standard of care in treating traumatic hemo-pneumothorax. The use of an endotracheal tube and a hand pump could offer portability and logistical advantages in the field setting.

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